In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
E-Filed: November 8, 2010
No. 03-295V

TONYA L. JARVIS,	*	
	*	PUBLISHED
Petitioner,	*	
	*	
	*	Hepatitis B Vaccine; Allegations
	*	of Left-Sided Weakness; Treating
v.	*	Doctors Suspect a Factitious
	*	Condition; Minimal Objective
SECRETARY OF THE DEPARTMENT	*	Evidence of a Neurological Injury
OF HEALTH AND HUMAN SERVICES,	*	
	*	
	*	
Respondent.	*	
	*	

Clifford Shoemaker, Vienna, VA, for petitioner.

Melonie McCall, Washington, DC, for respondent.

DECISION[1]

Campbell-Smith, Special Master

On February 7, 2003, petitioner, Tonya Capel Jarvis, filed a petition seeking compensation under the National Vaccine Injury Compensation Program[2] (the Vaccine

[1] Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless the decisions contain trade secrets or commercial or financial information that is privileged or confidential, or the decisions contain medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. Within 14 days of the filing of a decision or substantive order with the Court, a party may identify and move for the redaction of privileged or confidential information before the document's public disclosure.

Program or the Act). Petitioner alleged that as a result of a hepatitis B vaccination received on October 2, 2000, she "developed a RHEUMATOLOGICAL/SKELETAL injury, specifically, Arthralgias (Joint Pain)." Petition (Pet.) at 1, ¶¶ 5-6.

The Vaccine Act authorizes an award of compensation for a vaccine-related injury. 42 U.S.C. § 300aa-10(a). To receive such award, the petitioner must have received a vaccine listed on the Vaccine Injury Table (initial table) set forth at 42 U.S.C. § 300aa-14(a) and 42 C.F.R. § 100.3 (updated table). If the alleged injury is listed on the Table and the injury occurred within the time period set forth in the Table, petitioner's claim is deemed a Table case and a rebuttable presumption of causation attaches. See 42 U.S.C. § 300aa-11(c)(1), -13(a)(1)(A); 42 U.S.C. § 300aa-14(a). If, however, the alleged injury is not listed on the Table or the injury occurred beyond the identified time frame, petitioner's claim is deemed an off-Table case, and petitioner must prove that her injury was caused in fact by the received vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I).

Because Ms. Jarvis has asserted an-off Table claim, she must prove her claim by providing evidence that shows: "(1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury." Althen v. Sec'y of Dep't of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Important to the undersigned's evaluation of petitioner's claim of vaccine-related causation are two issues. The first involves clarifying the particular condition for which petitioner seeks Program compensation. The second involves identifying reliable and objective evidence that petitioner in fact suffers from the alleged condition. Questions about whether petitioner's condition in fact exists are expressed in the medical records prepared by petitioner's own treating doctors. Petitioner's treating doctors noted that the inconsistencies between petitioner's presentation and petitioner's neurological examination suggest that petitioner's condition is a "factitious" one.[3]

Having carefully reviewed the filed medical records and scientific articles and having carefully considered petitioner's testimony as well as the testimony of the parties'

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[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. § 300aa-10-§ 300aa-34 (2006) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

[3] A factitious condition is an "artificial" rather than a natural one. See Dorland's Illustrated Medical Dictionary 682 (31st ed. 2007).

experts, the undersigned concludes that the record as a whole does not support a finding for petitioner of entitlement to compensation. The reasons for this decision are set forth below in greater detail.

I. Procedural History

Shortly after the filing of petitioner's claim in 2003, the Office of Special Masters (OSM) considered grouping together a number of hepatitis B vaccine cases (involving allegations of similar injuries) for coordinated handling through omnibus proceedings. In anticipation of the omnibus proceedings, this petition was grouped with other vaccine claims in which similar symptoms were alleged. After the discontinuation in 2006 of efforts to conduct omnibus proceedings to resolve various hepatitis B claims, the record in petitioner's case began to be developed for individual resolution.

Following a three-year period of record development, two hearings were conducted in this case. The first hearing, a fact hearing,[4] served to assist the undersigned in evaluating the veracity of petitioner's allegations. That hearing was conducted in September 2007 in Washington, DC. The second hearing was an expert hearing. At the request of the undersigned, the parties' experts devoted a portion of their testimony to addressing what, if any, evidence, exists showing that petitioner has suffered a neurological injury. That hearing was conducted, again in Washington, DC, in June 2009. After the second hearing, the parties submitted post-hearing briefing. This case is now ripe for a ruling.[5]

II. Questions Regarding the Nature of Petitioner's Claimed Injury

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After petitioner received her second hepatitis B vaccine and prior to the filing of her vaccine claim, petitioner sought and received treatment from a number of physicians for complaints of headaches, left-sided weakness and numbness. Consistent with the requirements of the Act, the undersigned has reviewed carefully the record in this case and has considered the particular documents on which the parties have relied in support

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[4] The fact hearing was conducted to address the expressed concerns of petitioner's first expert, Dr. Joseph Bellanti, regarding petitioner's credibility.

[5] The undersigned is mindful of the delay in the issuance of this decision. The matter became ripe for decision while the undersigned completed her decision in Mead v. Secretary of Health and Human Services, No. 03-215, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010), one of the autism test cases in the Omnibus Autism Proceeding. Upon issuance of the decision on March 12, 2010, the undersigned has turned to pending non-autism matters awaiting decision. The undersigned regrets the delay in the issuance of this decision.

of their respective positions. The undersigned does not repeat the entirety of petitioner's post-vaccinal medical history in this ruling but does set forth those aspects of petitioner's various medical evaluations that have triggered questions about the nature of petitioner's claimed injury, specifically whether petitioner's described symptoms arise from an underlying neurological injury caused by her receipt of the hepatitis B vaccine or a psychiatric condition.

Questions about the nature of petitioner's injury first were raised by petitioner's own treating physicians. The medical records indicate that in addition to relating different accounts of the post-vaccinal events to her medical examiners, petitioner presented to the examiners with complaints that were not consistent with the limitations that petitioner demonstrated during her neurological examinations.[6] The noted inconsistencies caused petitioner's various examiners to question whether her condition was merely embellished or whether in fact her condition constituted a "factitious disorder." As defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV, a "factitious disorder" is "a mental disorder characterized by repeated, intentional simulation of physical or psychological signs and symptoms of illness for no apparent purpose other than obtaining treatment. It differs from malingering in that there is no recognizable motive for feigning illness." Dorland's at 556 (referencing the DSM-IV).

Similar questions about the nature of petitioner's claimed injury were posed by the first expert witness retained by petitioner. That witness, Dr. Joseph Bellanti, an immunologist, prepared an opinion of causation that was contingent upon a predicate finding that petitioner's assertions concerning her injury were credible. See P's Ex. 24. Dr. Bellanti did not testify at hearing.

The same questions raised by petitioner's treating doctors and posed again by Dr. Bellanti also were addressed directly by the parties' experts, Dr. Carlo Tornatore for petitioner and Dr. Thomas Leist for respondent, during the second hearing held in this case. See Tr. II at 22, 40, 43, 49, 80, 116-117. Because the issues raised by a few specific medical records were of particular importance to the testifying experts giving

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[6] In addition to the inconsistencies in petitioner's medical records, her later-offered testimony conflicted with her earlier given medical history as documented in the contemporaneous medical records. Contemporaneous medical records are afforded a presumption of accuracy that can be rebutted by evidence of irregularity or error in the records. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) (Conflicting oral testimony is afforded less evidentiary weight than written medical records.). In the absence of any rebuttal evidence here, the undersigned affords petitioner's records the presumption of accuracy that generally attaches to contemporaneous medical records.

medical opinions in this case, the undersigned examines these records more closely below.

III. The Factual Basis for Petitioner's Claim

Petitioner testified that she was in good health and that she did not recall having any medical problems prior to her receipt of the hepatitis B vaccination at issue in this case. Transcript of Fact Hearing held on September 14, 2007 (Tr. I) at 6-7. Petitioner's medical records confirmed that she had no significant prior medical history, see Petitioner's Exhibit (P's Ex.) 3 at 109, but the records did reveal that she had a history of allergic reactions to certain medications. P's Ex. 3 at 107. Petitioner's medical records show that she reported developing hives, tongue swelling, and headaches after her exposure to the medications Amoxicillin[7] and Compazine,[8] in particular. See id. at 15.

In 2000, petitioner began working at Walter Reed Child Development Center. Tr. I at 5. At that time, she was 30 years of age. See id. (referencing petitioner's birth date). Petitioner worked at the child development center first as a day care provider and then as an administrative clerk. Id. at 6.

As a requirement of petitioner's employment with the child development center, she received her first hepatitis B vaccination on August 30, 2000. P's Ex. 1 at 1; Tr. I at 7. She also received an inactivated polio vaccine. Id. Petitioner testified at hearing that she developed a fever after she received these vaccinations. Tr. I at 7.

On October 2, 2000, a little over one month after petitioner's first hepatitis B vaccination, petitioner received a second hepatitis B vaccine and an inactivated polio vaccine in her left arm. P's Ex. 1 at 2; Tr. I at 8. According to petitioner, the staff at Walter Reed Army Medical Center directed her to wait for ten minutes after the vaccinations. Tr. I at 9. As petitioner and a friend (who also was vaccinated) prepared to leave the medical center, petitioner advised her friend that she felt warm. Id. Petitioner's friend located a nurse to whom petitioner reported that she felt slightly warm. Id. The nurse acknowledged that a fever could occur after vaccination and advised petitioner to

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[7] Amoxicillin is used to treat bacterial infections. See http://www.drugs.com/amoxicillin.html

[8] Compazine is used to treat control severe nausea and vomiting and is also used on a short-term basis to treat anxiety that could not be controlled by other medications. Compazine, which is also known as prochlorperazine, is in a class of medications called conventional antipsychotics. It works by decreasing abnormal excitement in the brain. See http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000582

take a fever reducer such as Tylenol or Advil. Id. Petitioner then returned to work at the child development center. Id.

Once she returned to work, petitioner complained of a high fever. Id. at 10. She went home for the afternoon and continued to feel feverish and to experience a painful headache. Id. at 10-12. On October 4, 2000, two days after the vaccinations at issue, petitioner returned to work with a rash on her face, a fever, and a developing headache. Id. at 12-13. The assistant director of the child development center directed petitioner to see Dr. John Moore at the Walter Reed Army Medical Center. See id. at 14.

Dr. Moore examined petitioner and ordered a series of tests. See P's Ex. 25. Noting that petitioner had developed a malar rash thirty hours after her double immunizations, Dr. Moore suspected that petitioner had experienced an allergic reaction to the received vaccinations. See P's Ex. 17 at 526. Also included in the records detailing petitioner's examination by Dr. Moore were notations that petitioner "developed a high fever and delirium (seeing things, screaming and crying) and severe headache about one hour after receiving hepatitis B #2 and IPV."[9] Id. Dr. Moore's notes indicate that petitioner received the vaccine at two o'clock in the afternoon.[10] Id. At the time of Dr. Moore's examination, petitioner presented with tingling in her face as well as tingling on the left side of her body. Dr. Moore diagnosed petitioner with a "probable vaccine adverse event," id., and directed her to take Benadryl and Tylenol with codeine to address her symptoms, to get some bed rest, and to increase her fluids. Tr. I at 16-17; 50-51.[11] He also directed petitioner to report to a civilian doctor. P's Ex. 17 at 526. Dr. Moore advised petitioner to return to the clinic if she did not improve in 24 hours. He further advised that if petitioner's temperature increased to more than 102 degrees and she continued to experience a headache, petitioner should report promptly to the emergency room. Id.

Petitioner testified that after seeing Dr. Moore, she "stayed at [her mother's] house for several days [b]ecause for some reason, the fever would just not go away, or the headaches." Tr. I at 18. Petitioner did not seek medical care again until October 13, 2000, nine days after her examination by Dr. Moore.

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[9] At the fact hearing held in this case, petitioner recalled that she had cried during her examination at Walter Reed due to her fever. Tr. I at 15. But she did not recall screaming or seeing things. Id.

[10] Again the contemporaneous medical records conflict with petitioner's later-recalled details of the vaccination and the ensuing events. At the fact hearing, petitioner testified that she did not receive the vaccines in the afternoon. Tr. I at 8.

[11] The medical records reflect that Dr. Moore recommended Tylenol but do not contain any reference to a recommendation that petitioner take Benadryl. P's Ex. 17 at 526.

At hearing, petitioner asserted that she began to experience numbness in her left arm and hand on or about October 13, 2000, approximately 11 days after she had received the vaccine at issue. Tr. I at 19. She testified that on that same day, at the urging of the assistant director of the child development center, petitioner spoke with Dr. Moore again at the Walter Reed Army Medical Center. Tr. I at 20. On the recommendation from Dr. Moore that petitioner obtain a neurological examination, petitioner consulted with Dr. George Gluz.

The medical records reflect that Dr. Gluz examined petitioner on October 13, 2010, for an allergic reaction to hepatitis B and polio vaccine. See P's Ex. 3 at 114. In the medical records from this visit, Dr. Gluz specifically noted that the purpose of petitioner's office visit was to follow-up on an apparent allergic reaction that petitioner experienced after she received her second hepatitis B and polio vaccinations. Id. He further noted that petitioner developed a headache and a fever of 101 degrees as well as tingling on the left side and left arm pain at the site of the shot two days after receipt of the vaccination. Id. Dr. Gluz added that petitioner subsequently developed tongue swelling and tingling of the mouth. Id. Dr. Gluz referred petitioner to Dr. Daniel Glor, a neurologist.

On referral from Dr. Gluz, petitioner saw Dr. Glor, who first examined her on October 24, 2000. See P's Ex. 15 at 31-32. Petitioner presented to him with complaints of left-sided pain that affected her face, her arm, and her hand. Id. at 31. Dr. Glor wrote in his notes that petitioner had developed a fever of 102 degrees on the day that she received her second hepatitis B vaccination, and that she had developed tongue swelling and headaches over the next few days. Id. at 31. Dr. Glor reported that petitioner's cranial nerves were normal. Id. at 32. But, he observed, petitioner had decreased sensation in the left side of her face. Id. He added that her left-sided strength could not be assessed because petitioner's described pain caused her to reduce the level of her exerted effort. See P's Ex. 15 at 32.

On the same day that Dr. Glor first examined petitioner, petitioner was admitted to the hospital for a four-day stay. On admission, her temperature was 99 degrees Fahrenheit, and her white cell count was 11,000, a slightly elevated cell count that could be attributable to infection or inflammation as well as to trauma or stress – whether emotional or physical. See P's Ex. 15 at 41-42; see also Mosby's Manual of Diagnostic and Laboratory Tests 549 (4th ed. 2010). A head computed tomography (CT) scan, which is helpful for an early evaluation of head trauma, was normal. P's Ex. 15 at 42; see also Mosby's at 1080. A magnetic resonance image (MRI) taken of petitioner's brain and an administered electroencephalogram (EEG), measuring petitioner's brain wave activity, were normal. See P's Ex. 4 at 201, P's Ex. 17 at 139. Petitioner refused to submit to a lumbar puncture during her hospitalization in spite of recommendations from both the internist and the neurologist who examined her. See P's Ex. 17 at 139, P's Ex.

15 at 42. Other administered tests for particular antibodies, such as antinuclear antibodies (ANA), were negative.[12] P's Ex. 4 at 192. On discharge from the hospital, petitioner was given a walker. P's Ex. 3 at 104. Her hospital discharge summary included a notation that one of petitioner's examining neurologists suggested that prior to discharge, "the patient might benefit from a psychiatric consultation." P's Ex. 15 at 42.

Dr. Glor conducted another neurological examination of petitioner on December 13, 2000, approximately six weeks after petitioner's hospital admission and more than ten weeks after her hepatitis B vaccination. P's Ex. 3 at 105. Petitioner reported less intense pain, but reported three falls that had been preceded by left leg weakness. Dr. Glor wrote: "Patient is improved compared to her state on [October 24, 2000]. The exact etiology of her symptoms is unclear. There are some inconsistencies in her neuro[logical] exam." P's Ex. 3 at 105.

Petitioner's treating neurologist Dr. Glor referred petitioner to Dr. Richard Johnson, a neurologist at Johns Hopkins School of Medicine, for further examination. See Tr. II at 33. In August 2001,[13] petitioner saw Dr. Johnson. See P's Ex. 17 at 98. Dr. Johnson's impression was a strong one: "The examination is remarkable in the embellished and factitious nature of her physical findings." P's Ex. 22 at 116. In Dr. Johnson's view, petitioner behaved inconsistently with her alleged complaints on examination. He specifically noted that: "She can hold her hands up in a steady position and moves the left arm quite well, but on direct testing, has great weakness and on testing of position sense, denies any position sense in the hand, even though it remains in normal posture with eyes closed. . . . She denies virtually any pain or sensation over the left side of the face, and it is very peculiar in that the line of demarcation of sensation is not midline[], nor is it on the physiological side . . . . [I]n fact, it goes the opposite direction so that the anesthesia crosses the midline to the normal a[n]esthetic side. There is not a

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[12] A positive finding of such antibodies might assist an examining physician in diagnosing an autoimmune condition, such as rheumatoid arthritis or systemic lupus erythematosus. See Mosby's at 90-91.

[13] The records of petitioner's evaluation by Dr. Johnson are dated respectively August 8, 2001 and September 10, 2001. See Tr. II at 33. It is undisputed, however, that petitioner saw Dr. Johnson on only one occasion. See id. A review of petitioner's medical records from Dr. Glor indicates that petitioner's visit to Dr. Johnson occurred on August 8, 2001. P's Ex. 17 at 98. Dr. Glor's notes also reflect that he spoke with Dr. Johnson on September 4, 2001, regarding petitioner's visit. Dr. Johnson reported to Dr. Glor that his notes were "lost in the J[ohn]H[opkins]U[niversity] system" and he planned to dictate his notes a second time. Id. The undersigned does not rely on the records to establish the date of treatment but rather for the purpose of determining what was Dr. Johnson's impression of petitioner's alleged injury.

left facial weakness." Id. Dr. Johnson concluded that "[a]ll of the major findings are apparently fictitious." P's Ex. 17 at 191. But, he allowed, "whether [Ms. Jarvis] has some underlying disease and this is being embellished for the examiner, I have no idea." Id. Dr. Johnson recommended testing of petitioner's spinal fluid "to see if there [was] any underlying problem." Id. In his assessment, however, "the major differential diagnosis would be between hysteria and malingering." Id.

On August 9, 2001, petitioner's mother called Dr. Glor's office and indicated that petitioner was worse. P's Ex. 17 at 109. Petitioner was dragging her left leg, and experiencing pain and spasms. Id. Her mother was afraid to leave her alone. Id. Noting that Dr. Johnson had convinced petitioner to have a lumbar puncture to test her spinal fluid, Dr. Glor admitted her to the hospital. Id. at 109-110.

On admission to the hospital, a lumbar puncture was performed, and petitioner's cerebrospinal fluid was tested. P's Ex. 17 at 481. The results were entirely negative. P's Ex. 17 at 102. Nor was there any evidence of a lesion detected. The repeat MRI of the brain was normal, see P's Ex. 17 at 106, as was the MRI of the lumbar spine. P's Ex. 4 at 111; see also P's Ex. 17 at 108.

In the discharge summary, the examining physician wrote:

> The thought at this time is that [petitioner] probably does have a progressive neurologic syndrome secondary to the vaccine, most likely hepatitis B. [H]owever, no documentation of this has been made. The diagnosis at this time is simply her [symptoms] were [of] unclear etiology.

P's Ex. 4 at 111 (emphasis added).

On August 15, 2001 petitioner was discharged from the hospital with a diagnosis of "[p]ossible polyneuropathy/paresthesias, presumably secondary to vaccination." P's Ex. 4 at 109. From the hospital, petitioner was transferred to a rehabilitation facility, where she received physical therapy, occupational therapy, and speech therapy. P's Ex. 17 at 108. Petitioner was discharged from the rehabilitation facility on August 31, 2001. See P's Ex. 17 at 99.

Dr. Glor subsequently discussed petitioner's case with Dr. Johnson. P's Ex. 17 at 98. Dr. Johnson, who had found "several factitious signs on [his] exam[ination] " of petitioner, related to Dr. Glor that petitioner had reported an onset of her numbness within twenty minutes after receiving her immunizations, and in his view, such timing would be inconsistent with a post-vaccinal encephalomyelitis. Id. In response to Dr. Johnson's communication, Dr. Glor noted in his records that the history petitioner provided to Dr. Johnson was different from the history that petitioner had provided to him during his initial consultation. Petitioner had reported to Dr. Glor that she received

her second hepatitis B immunization on October 2, 2000, but that her left-sided tingling did not start until 18 days later on October 20, 2000.[14] Id.

In February 2002, more than five months after petitioner was discharged from the rehabilitation facility, she returned to the hospital seeking treatment for left-sided burning pain accompanied by a "needle[-]sticking" sensation. P's Ex. 17 at 75. The examining physician, Dr. Robyn Anderson, made observations that were remarkably similar to the observations that Dr. Johnson had made five months earlier regarding petitioner's inconsistent behavior on examination. Dr. Anderson wrote in his notes: "31 y[ear] o[ld] woman with [a history of] bizarre neurologic complaints including left[-]sided weakness [and] parasthesias . . . . Exam notable for left foot dragging, but able to walk normally when instructed to do so." P's Ex. 22 at 33. Dr. Anderson's hospital discharge note indicates that petitioner's "[l]abs [were] all normal, [and her] MRI brain/c[ervical]-spine/L[umbar]-S[pine] [were] all normal." Id. Dr. Anderson offered a diagnosis of pain and recommended that petitioner consider a pain clinic consult for her chronic pain issues. P's Ex. 22 at 33.

Four months later, on June 17, 2002, Dr. Brian Schulman, a physician board certified in psychiatry and neurology, evaluated petitioner in connection with the workers' compensation claim initiated with her employer, Walter Reed Child Development Center.[15] Dr. Schulman observed:

> [T]he record is replete with the results of numerous neurodiagnostic studies, all of which have failed to reveal any evidence of underlying organic pathology or, more specifically, any indication that [petitioner] suffered with a neurologic or a metabolic reaction to her immunization. Her response is entirely behavioral, suggestive of a psychogenic reaction.

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[14] Dr. Glor's initial consult note dated October 24, 2000, provides that petitioner "over the last few days has developed swelling of the left arm, weakness of the left leg, and tingling in the left fingers and toes. She also continues to have fevers." P's Ex. 17 at 140.

[15] Dr. Schulman's report also references an neurologic evaluation that was performed by Dr. Bruce Ammerman for Worker's Compensation on April 2, 2001. P's Ex. 21 at 15; see also P's Ex. 17 at 121. It appears from Dr. Schulman's report that Dr. Ammerman also viewed the symptoms of which petitioner complained to be "an unusually bizarre reaction to an immunization." P's Ex. 21 at 15. Dr. Ammerman questioned whether there was any functional component underlying petitioner's symptoms and he too recommended a psychiatric consultation. See P's Ex. 21 at 15.

P's Ex. 21 at 15 (emphasis added). Dr. Schulman was persuaded that petitioner had shown signs of a factitious disorder, a classified mental disorder in the DSM-IV, the most current edition of the diagnostic manual used by mental health professionals.[16] Id. Dr. Schulman's opinion, as expressed with reasonable medical certainty, was that petitioner's well-documented clinical presentation "greatly exceed[ed] any evidence of underlying organic impairment, particularly what might specifically be experienced following an adverse immunization reaction." Id. at 16.

Dr. Schulman had no specific recommendations for petitioner's additional treatment because it was his view that her condition was not caused by the alleged work-related event of vaccination. P's Ex. 21 at 16. Dr. Schulman stated that "Factitious Disorders are illnesses of life" and "present with a dramatic flare, often after some unusual event." Id. The symptoms "are often equally unusual and do not correlate with any known organic syndrome." Id. Dr. Schulman noted that this "disorder is not usually amenable to any medical intervention and frequently gets 'worse' in response to medical treatment." Id. In fact, "confrontation and discontinuation of extraneous or unnecessary treatments are often the most prudent course of action." Id.

In addition to her other consultations, petitioner was examined again by Dr. Glor on December 13, 2001, February 7, 2002, June 28, 2002, September 11, 2002, and January 30, 2003. See P's Ex. 3 at 24, 25, 33-37, 50-51. Petitioner complained of intermittent pain at all of these visits, with no major change in her symptoms or pain level.[17] Petitioner stopped seeing Dr. Glor after January 2003 because she lost her insurance coverage with Kaiser when she was terminated from her job with Walter Reed Child Care Center. Tr. I at 37. Since discontinuing her treatment with Dr. Glor, petitioner has not sought further medical attention for her alleged vaccine-related condition of one-sided weakness.

The medical records show that petitioner was treated for many symptoms including but not limited to pain, weakness, numbness, muscle spasms, and difficulty walking after her receipt of the hepatitis B and polio vaccinations on October 2, 2000. See generally e.g., P's Ex. 3; P's Ex. 17. However, what emerges from a review of the medical records is that there is scant objective evidence of neurologic abnormality.

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[16] The DSM-IV is published by the American Psychiatric Association.

[17] Dr. Glor mentions in his record of petitioner's June 28, 2002 visit, P's Ex. 3 at 35-37, that he received a seventeen page report from Dr. Brian Schulman, a psychiatrist and neurologist. Based on that report, the insurance company handling petitioner's worker's compensation claim denied petitioner further benefits.

IV. The Applicable Legal Standards

To prevail on her vaccine claim, petitioner must show that she would not have been injured but for her vaccination and that the vaccination was a substantial factor in bringing about her injury. Shyface v. Sec'y of Dep't of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Petitioner must present a medical theory that is supported either by medical records or by the opinion of a competent physician. Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Proof of vaccine causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Grant, 956 F.2d at 1148 (medical theory must support actual cause). Mere temporal association is not sufficient to prove causation. Grant, 956 F.2d at 1148.

The preponderance of evidence standard under the Vaccine Act requires proof that a vaccine more likely than not caused the vaccinee's injury. Althen, 418 F.3d at 1279. A petitioner may use circumstantial evidence to prove her case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280.

In evaluating petitioner's vaccine claim, a special master may consider the opinions of petitioner's treating doctors. Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Moreover, in evaluating whether a petitioner has presented a legally sufficient medical theory, "the special master may require some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324. When the opinion of the expert reflects an extrapolation from existing data and knowledge, and the gap between the science and the opinion proffered is connected "only by the ipse dixit of the expert," a special master may find the offered opinion too speculative. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

V. The Respective Positions of the Parties' Experts

1. Dr. Carlo Tornatore, Petitioner's Expert

Petitioner's expert, Dr. Carlo Tornatore, a neurologist, currently serves as the director of the Multiple Sclerosis Clinic at Georgetown University Hospital. Transcript of Expert Hearing held on June 23, 2009 (Tr. II) at 7, 9. He also serves as the director of the residency program for the medical students. Id. at 9. In that capacity, he assists in instructing medical student on the use of medical tests, on the interpretation of those tests, and on the limitations of the tests. Id. In addition, he runs the clinical clerkship program for medical students, and in that capacity, he helps train medical students to conduct

neurologic examinations.[18] Id. at 9-10. The undersigned accepted Dr. Tornatore as an expert in the field of neurology.

Initially, Dr. Tornatore opined in his written report that petitioner had suffered "an episode of transverse myelitis in the high cervical area" of her spinal cord. P's Ex. 29 at 2. He explained that transverse myelitis "is a rare clinical syndrome in which an immune-mediated process causes neural injury to the spinal cord, resulting in varying degrees of weakness, sensory alterations and autonomic dysfunction." Id. Dr. Tornatore further explained that "[t]he term myelitis refers to inflammation of the spinal cord[, and] transverse describes the position of the inflammation" across the width of the spinal cord. Id. In support of Dr. Tornatore's written report, petitioner filed 13 medical references. See P's Exs. 30-43. Eleven of the filed references addressed the development of transverse myelitis after vaccination. See P's Exs. 31, 32, 33, 35, 36, 37, 38, 39, 40, 41, 43. Five of the filed references specifically addressed the development of transverse myelitis after receipt of the hepatitis B vaccine. See P's Exs. 33, 35, 36, 39, 40.

At hearing, however, Dr. Tornatore appeared to abandon his earlier asserted diagnostic impression of transverse myelitis. He instead described petitioner's injury more generally—opining that the hepatitis B vaccines that petitioner received first on August 30, 2000, and then on October 2, 2000 "resulted in a syndrome of . . . left-side[d] weakness" that was "probably inflammatory in nature." Tr. II at 12. Although the injuring insult was a "one-time event," Dr. Tornatore opined that it "left Ms. Jarvis with chronic neurologic signs and symptoms." Id. at 12-13.

Dr. Tornatore testified that Ms. Jarvis experienced "an inflammatory event that caused inflammation in the brain that resulted in neurologic symptoms." Id. at 13. He explained that the second hepatitis B vaccination boosted her already "primed" immune system. Id. at 14. He opined that as a result of the hepatitis B vaccine that Mrs. Jarvis received, "there was enough inflammation that it hit a part of the brain that [led] to the pain and the weakness." Tr. II at 55. He added that the two to three week time frame between petitioner's vaccination and the development of additional symptoms after what appears to have been an initial allergic reaction to the vaccine "is right." Id. at 57. He

[18] Prior to his employment at Georgetown, Dr. Tornatore spent six years at the National Institute of Neurological Disorders and Stroke at the National Institutes of Health in Bethesda, Maryland. There, he participated in research concerning "how viruses infect the brain [and] how microbacteria interact with the immune system." Tr. II at 8. The virus of interest in his research was the human immunodeficiency virus (HIV). Id.

Well-published, Dr. Tornatore is a listed author on nearly 50 medical articles, including both primary papers and review articles. Id. at 10-11.

explained that in this case, "[w]e're well within the time frame of an area [in which] we can hypothesize now that there was an area of inflammation." Id.

In support of the biological mechanism of harm that he proposed, Dr. Tornatore referred to several notations in petitioner's medical records. He pointed first to the record of petitioner's evaluation in the Allergy and Immunology Center at Walter Reed shortly after petitioner received her second hepatitis B vaccination. Tr. II at 14-15; P's Ex. 17 at 526. Of importance to Dr. Tornatore was the documented appearance of a malar rash on both sides petitioner's face.[19] In Dr. Tornatore's view, this was evidence of an allergic reaction and according to petitioner's medical records, was assessed as a "[p]robable vaccine adverse event." Tr. II at 16; P's Ex. 17 at 526. Dr. Tornatore added that although the medical records do not explicitly acknowledge petitioner's symptom of left-sided tingling as a probable vaccine adverse event, it is his belief that the documented complaint of tingling was another indication of an adverse vaccine event. See Tr. II at 16.

Dr. Tornatore also pointed to the petitioner's early blood screen that yielded a high reading for antinuclear antibodies (ANA). Tr. II at 16-17; P's Ex. 17 at 506. A positive presence of ANAs may be indicative of an autoimmune disorder, in particular systemic lupus erythematosus. See Mosby's at 91. Such positive results were not obtained again during later testing, but Dr. Tornatore asserted that the early test result offered evidence that petitioner's "immune system was activated." Tr. II at 17. Similarly, petitioner's early test results showed a slightly elevated bilirubin level, a finding that Dr. Tornatore explained was indicative of either liver problems or inflammation of the red blood cells (from which bilirubin is metabolized). Id.; see also Mosby's at 134-135. This early test result of a slightly elevated bilirubin level does not occur again; rather, petitioner's subsequent laboratory test results for bilirubin were "completely normal." Tr. II at 17.

Other indicators, in Dr. Tornatore's view, that petitioner's alleged injury "was real" were the medications that petitioner's treating doctors prescribed for her. See Tr. II at 23-24. Among the prescribed medications were narcotics intended to treat pain. Id. at 24, 26-27. Dr. Tornatore asserted that because narcotic medication has the "potential for problems and abuse," physicians do not prescribe them "lightly." Id. at 27.

The "most striking" indication, in Dr. Tornatore's view, that petitioner's neurologic symptoms were "bona fide" was her response to a nerve conduction study performed at Dr. Glor's request in September 2001. Tr. II at 31; P's Ex. 3 at 75-80. Dr. Glor noted that "[t]he patient hardly felt the shocks from the [nerve conduction study] machine in her left leg, which in my mind confirms she's numb on the left side." Tr. II at

[19] A malar rash is one that appears on the cheeks. See Dorland's at 1112; see also id. at 1617.

32 (quoting P's Ex. 3 at 75). Dr. Tornatore observed that in contradistinction to the "painful shocks" that are administered during a nerve conduction study, all the other performed neurological tests, including the Hoover's sign,[20] are "soft" tests.[21] Tr. II at 31-32.

Dr. Tornatore added that one of the observations of Dr. Johnson, one of petitioner's consulting neurologists, detailed in his examination notes was not an indication "that Ms. Jarvis was faking her weakness but in fact [was] a true demonstration of . . . weakness." Id. at 34. The observation to which Dr. Tornatore referred was Dr. Johnson's record notation that petitioner had demonstrated "weakness" when "turning her head to the left, [a movement] suggesting a weak right sternocl[eido]mastoid [muscle] and a strong left one." P's Ex. 17 at 187.

Dr. Tornatore explained that when the sternocleidomastoid (the muscle running "from just below the ear to the collarbone") contracts, it causes the head to turn. Tr. II at 35; see also R's Ex. F (S. Zelton, et al., Photograph of the Sternocleidomastoid, "Learning Muscles by Building them with Clay" http://www.myeport.com/published/c/la/clay/tdocuments 23/(last visited Nov. 5, 2010)). Dr. Tornatore relied on the results reported in a study filed as Petitioner's Exhibit 45,[22] the Mastiglia article, to characterize Dr. Johnson's observation regarding petitioner's ability to turn her head as a "kind of rookie error" and "absolutely incorrect." Tr. II at 34, 35.

The Mastiglia article detailed the findings from a study of 40 patients who—similar to petitioner in this case—demonstrated one-sided muscular weakness—but unlike petitioner in this case—also presented with a cerebrovascular lesion. See P's Ex.

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[20] The Hoover's sign is an anatomical phenomenon observed in a patient lying on a flat surface. When the patient is directed to press one of her legs against the surface (using her heel), the opposite limb will lift involuntarily from the surface if the patient is in either a natural state or a state of genuine paralysis. See Dorland's at 1737; R's Ex C (J. Stone & M. Sharpe, Hoover's Sign, Practical Neurology 50, 51 (2001)). The phenomenon is absent in a patient who is either hysterical or malingering. Dorland's at 1737; R's Ex. C at 50-52 (2001 Stone article).

[21] A nerve conduction study assists in the detection and location of peripheral nerve injury by determining the conduction velocity of an electrical impulse sent through a nerve. Mosby's at 581. Slow conduction velocity may be indicative of an injury. Id. at 582. Because the test is performed by initiating an electrical impulse (or shock) along a nerve fiber, the test is acknowledged to be an "uncomfortable" one. Id.

[22] F. L. Mastaglia et al., Weakness of Head Turning in Hemiplegia: A Quantitative Study, Journal of Neurology, Neurosurgery, and Psychiatry 49: 195-197 (1986).

45 at 195. Dr. Tornatore testified that, as reported by the researchers conducting that study, a majority of patients with one-sided weakness (hemiparesis) attributable to a lesion in the cerebral hemisphere, show weakness in turning their heads away from the lesion. Tr. II at 36-37; P's Ex. 45 at 196. Explaining that left-sided weakness develops as a result of a "problem on the right side of the brain," Dr. Tornatore asserted that the detection of weakness in Ms. Jarvis's right neck muscle rather than in her left neck muscle actually supports a finding that Ms. Jarvis has an underlying neurological problem. See Tr. II at 37-38. Dr. Tornatore did not discuss, however, why reliance on the findings in the Mastiglia article that involved patients with one-sided weakness that was unquestionably associated with an existing cerebrovascular lesion was appropriate in this case in which petitioner presented with one-sided weakness in the absence of a cerebrovascular lesion.

Persuaded that petitioner had experienced an adverse inflammatory event after her vaccinations, Dr. Tornatore pointed to several indicators that petitioner's immune system demonstrated a response after the administered vaccinations. But he admitted that no "obvious inflammatory lesions" were detected in the images taken of petitioner's brain. Tr. II at 23, 55. He also acknowledged during his testimony that the results of petitioner's other evaluative testing were "negative." Id. at 23.

Dr. Tornatore conceded that there were "inconsistencies" and "findings that [were] a little difficult to explain." Id. at 40. He further conceded that the reported results of petitioner's neurological examination by Dr. Johnson, whom Dr. Tornatore recognized as a "towering figure in neurology," id. at 34, included certain findings (notably "the Hoover sign, the tuning fork and changes over the forehead") that were recognizably "f[a]cititious." Id. at 39. Moreover, Dr. Tornatore observed that Dr. Glor, the neurologist who performed an early evaluation of Ms. Jarvis after the vaccinations at issue and "subsequently took care of [her] for some years," wrote in his own examination notes that he had detected "some inconsistencies." Tr. II at 22, 25.

Dr. Tornatore offered that "people who have real pain . . . may [also] embellish . . . and make it difficult" to evaluate the patient medically. Tr. II at 42. Urging that care must be taken when conducting such an evaluation, Dr. Tornatore quoted from the 2001 Stone article, filed as Respondent's Exhibit C, addressing the value of the Hoover's sign: "'There is still no reliable way of differentiating those patients who are deliberately deceiving you from the majority of patients who have little conscious control over their l[eg] weakness.'" Tr. II at 52 (quoting R's Ex. C at 52). Dr. Tornatore, in effect, urged reliance on petitioner's representations concerning her pain.

2. Dr. Thomas Leist, Respondent's Expert

Respondent's expert, Dr. Thomas Leist, a neuroimmunologist, currently directs the neurological service at the Multiple Sclerosis Center at Thomas Jefferson University

in Philadelphia, Pennsylvania.[23] Tr. II at 71-72. In his role at the Multiple Sclerosis Center, Dr. Leist treats patients with various neurological manifestations of immune syndromes such as transverse myelitis, chronic inflammatory demyelinating polyneuropathy, and multiple sclerosis. Id. at 73. In addition to treating patients, Dr. Leist serves as an associate professor of neurology conducting research and teaching both students and residents. Id. at 71-72. He holds a doctorate in biochemistry and his medical training reflects a particular emphasis in the area of immunology. Id. at 72. The undersigned accepted Dr. Leist as an expert in the fields of neurology and neuroimmunology.

Dr. Leist opined that petitioner "did not sustain a vaccine injury or a consequence of the neurologic consequence of the vaccine." Id. at 74. A number of factors informed Dr. Leist's opinion.

As an initial matter, Dr. Leist observed that petitioner had a history of particular allergic reaction to certain medications. He pointed out that prior to the receipt of petitioner's second hepatitis B vaccination, petitioner had reported an allergic reaction to amoxicillin that included hives, tongue swelling and headache. Id. at 75-76; see also P's Ex. 3 at 12. The symptoms described as part of petitioner's allergic reaction to amoxicillin are the same symptoms that petitioner reported experiencing after she received her second hepatitis B vaccination and, in Dr. Leist's view, are more suggestive of an allergic reaction rather than a neurological reaction to the administered vaccine.

Dr. Leist also observed that the timing of the onset of petitioner's alleged neurological symptoms of tingling in her left arm and left leg was not consistent with a new neurological injury, but was more consistent with the neurological course that results from a pre-existing lesion in the central nervous system. Tr. II at 77-78. The recorded accounts of the onset of petitioner's symptoms indicate that petitioner began experiencing tingling in her left arm and left leg between 20 minutes and two hours after she received her second hepatitis B vaccination. See Tr. II at 77; see also P's Ex. 17 at 526. Dr. Leist explained that because petitioner had no reported neurological symptoms prior to her vaccination, the appearance of neurological symptoms so quickly after vaccination indicates, "[f]rom an immunological point of view," that "an immediate onset lesion in the central nervous system" had occurred because the left arm and the left leg were affected. Tr. II at 77-78.

Moreover, the "immediate onset lesion" would have to have occurred "very high up" in the cervical region of the spinal cord or in the brain stem because petitioner also

[23] Prior to his employment with Thomas Jefferson, Dr. Leist worked at the National Institute of Health conducting immunology research and conducting clinical trials. Tr. II at 73.

was reported to have experienced delirium. Id. at 78. Dr. Leist noted that cognitive changes (which can include delirium) can occur in the presence of very high fevers, or appear before the offending lesions become apparent on magnetic resonance imaging of either the brain or the spinal cord. Id. at 78-79. Dr. Leist further noted that "[t]here are only very few places in the brain and in the spinal cord where you can have a hemianesthesia [(that is, one-sided loss of sensation)] or very significant signs of these symptoms on one side and weakness on the same side." Tr. II at 118. However, without the facial weakness and vascular involvement that typically accompany such neurological impairments and in the presence of preserved arm and leg coordination, such as petitioner demonstrated in this case, Dr. Leist stated that he could not identify either "the nature [of or] the location of the purported neurological injury" and thus, he could not conclude that the injury in fact had occurred. Id. at 119.

Dr. Leist asserted that for "a neurological injury as opposed to [a] psychiatric or psychological state" to be implicated in this case, lesions must be "present." Id. at 80. In this case, however, petitioner was afebrile when Dr. Glor took her temperature during her first neurological examination in October 2000, and no lesions were detected on magnetic resonance imaging (MRI) that was performed during her October 24-28, 2000 hospitalization. Id. at 79-80. That petitioner had several MRIs of both her brain and her spinal cord taken that failed to detect any lesions and that testing of petitioner's spinal fluid yielded normal results are significant factors, in Dr. Leist's view, rendering petitioner's alleged neurological injury "very unlikely." See id. at 90, 105, 111,118-119.

Other factors about petitioner's claim of a neurological injury troubled Dr. Leist as well. In particular, he noted that the reported changes in petitioner's level of sensitivity during her sensory testing and the reported changes in petitioner's presentation of weakness did not reflect either consistent changes or progressive changes. See id. at 95-96, 97-98. Dr. Leist opined that the reported changes in petitioner's sensitivity and weakness were, at best, more congruent with an ongoing "multifocal process" than with the monophasic process that petitioner's expert had described. See id. at 93-94, 95-96, 97-98, 117. He indicated that in the absence of any detectable lesions, such changes were difficult to explain medically. See id. at 95-96, 97-98. Additionally, Dr. Leist testified that the reported activities that petitioner could perform satisfactorily (including standing on a trampoline, squatting and rising from a squatting position, and independently using the bathroom) were difficult to reconcile with the various neurological assessments in petitioner's medical records noting her diminished strength. See id. at 81, 89, 91-92, 96-97, 107, 111.

When asked about the particular treatment that petitioner had received for her alleged pain from her treating neurologist Dr. Glor, Dr. Leist responded that he viewed Dr. Glor's treatment of petitioner to be consistent with what he "would expect from a physician that takes care of a patient." Id. at 115. Unable to objectively measure pain or to assess the severity of a patient's pain, a physician necessarily treats pain based on the

representations of the patient. Id. at 115-116. Dr. Leist also mused that Dr. Glor's impression of petitioner's case may have been affected by his perception that Ms. Jarvis's neurological symptoms first appeared 18 days after her hepatitis B vaccination rather than during the 20 minute to two hour time frame after she received the vaccination, as petitioner reported to Dr. Johnson during his neurological consultation. See id. at 113-114.

Dr. Leist explained that a neurological examination consists not only of direct testing, but also of close observation of the patient, for example, during the patient's entrance into the exam room and as the patient climbs onto the examining table. Id. at 121. Such observations also inform a careful examiner's assessment of a patient's neurological condition. While Dr. Leist allowed that subtle fluctuations could occur from day-to-day in neurological symptoms, he maintained that notable and inconsistent changes in neurologic symptomatology—such as exhibited by petitioner—conflict with current medical understanding of the course of such neurological injury and cannot be explained merely as the "subtle differences between examiners." See id. at 120-121, 124. Dr. Leist based his opinion of no vaccine-related causation on his detailed review of the successive neurological examinations that petitioner received, rather than on any particular medical record. See id. at 124, 129.

VI. The Althen Analysis

An analysis of petitioner's claim involves applying the three-pronged legal test articulated by the Federal Circuit in Althen to determine whether petitioner has established, on this record, that she suffered a vaccine-related injury.

1. Examining the Presented Medical Theory under Prong One

Prong one of Althen requires a petitioner to present a medical theory causally connecting her received vaccination to her injury. Althen, 418 F.3d at 1278. The theory advanced by petitioner must be a biologically plausible one and must explain how the vaccine received by the petitioner could cause the sustained injury. See Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009). This requirement has been interpreted to present the question of "can [the] vaccine(s) at issue cause the type of injury alleged?" Pafford, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (alterations in original).

The proposed theory of causation need not reflect scientific certainty. Moberly, 592 F.3d at 1322. Nor must it be corroborated by medical literature or epidemiological evidence. Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The theory, however, must have a scientific basis. A persuasive theory is a sound, reliable, and reputable one. See Andreu, 569 F.3d at 1379-80.

Dr. Tornatore opined initially in his expert report that petitioner had suffered an episode of transverse myelitis. The opinion was a singular one. A review of petitioner's medical records indicates that none of petitioner's various examining neurologists characterized her condition as transverse myelitis. Rather, her medical examiners described the condition of which she complained as one involving pain and variable weakness. Petitioner's medical examiners also expressed some skepticism concerning her reported complaints and openly questioned whether petitioner had embellished her condition during her examinations or whether an underlying psychiatric component might be operating.

At hearing, Dr. Tornatore expressed some uncertainty as well about the precise nature of petitioner's condition. He acknowledged that "there is a little bit of ambiguity of what the exact diagnosis is." Tr. II at 13. He did not elaborate during his testimony on his earlier expressed view that petitioner had experienced an episode of transverse myelitis. Instead, he opined at hearing that Ms. Jarvis's second hepatitis B vaccination had triggered an inflammatory event that affected her brain and led to the development of her pain and left-sided weakness. See Tr. II at 55.

He explained that petitioner's first hepatitis B vaccination "primed" her immune system. Tr. II at 56. He further explained that the prior stimulation of petitioner's immune system allowed her response to the second vaccination to occur more quickly—as evidenced by the "discomfort" petitioner experienced "several hours" after her vaccination. Tr. II at 56. Dr. Tornatore speculated that the stimulation of petitioner's immune system "in an inordinate way . . . was enough" to produce inflammation in petitioner's brain that caused petitioner to develop pain and weakness. Id. at 54-55.

The lack of any detected evidence of such inflammation in the MRIs taken of petitioner's brain did not affect Dr. Tornatore's opinion. He pointed to other neurological conditions—such as the progressive health conditions multiple sclerosis and Parkinson's disease—that present with "bona fide organic symptoms and signs," during early presentation, but show "very, very little" on brain imaging. See id. at 55. Noting also that "small discrete problems with the brain" can be difficult to detect, he averred that in this case, "[t]here's definitely a biologically plausible mechanism that we just couldn't pick up with all the tools we had available." Id. It was not clear from Dr. Tornatore's testimony, however, whether he attributed the difficulty in detecting the alleged inflammatory event in petitioner's brain to either the early timing of petitioner's presentation or the limited scope of the inflammatory event.

In response to Dr. Tornatore's assertions, respondent's expert, Dr. Leist, allowed that neurological injury could occur in individuals who had experienced "very high fevers" or who had suffered a widely distributed injury—known as "a multiple focal injury to the central nervous system." Id. at 78. He further allowed that "[s]ometimes in patients . . . [presenting with] cognitive changes, the cognitive changes precede the actual

manifestation of the lesions" on imaging. Id. at 79-80. However, he challenged the biological mechanism proposed in this case because the medical records do not indicate either that petitioner experienced "very high fevers" or that petitioner ever developed any lesions as a result of the inflammatory process that Dr. Tornatore described. See id. at 78-80.

The only medical literature that petitioner filed in support of her claim addressed the injury of transverse myelitis, a condition that petitioner has not been shown to have. The biological mechanism described in the filed literature pertaining to transverse myelitis is an inflammatory process that affects a restricted area of the spinal cord and is commonly detectable through magnetic resonance imaging and a lumbar puncture. See Petitioner's Exhibit 34 at 339-340 (D. Kerr & H. Ayetey, Immunopathogenesis of acute transverse myelitis, Neurology 339-347 (2002)). While petitioner need not have filed any medical literature in support of her claim, see Capizzano, 440 F.3d at 1326, the literature that she did file addressed both an injury and a manner of detecting the underlying inflammatory process that do not appear to be present in this case.

In addition, petitioner's expert has offered a bare assertion that a received hepatitis B vaccination could trigger an inflammatory event of sufficient magnitude to cause persistent one-sided weakness and pain, yet of sufficient limitation that the inflammatory event cannot be detected through laboratory testing or imaging. The soundness of the asserted causal theory that a neurological injury involving intermittent but marked physical limitations on one side of the body could occur and persist over time with scant evidence of neurological impairment is not demonstrated by a bare assertion. Support for petitioner's claim rests primarily with the opinion of causation offered by petitioner's expert, and, in the view of the undersigned, this evidence does not support a finding that petitioner more likely than not has offered a scientifically sound and reliable theory of causation. See General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997) (providing guidance that pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), a court may reject the testimony of an expert "that is connected to existing data only by the ipse dixit of the expert."); see also Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (recognizing that a special master may assess an expert's testimony using the Daubert factors). Because the proposed theory of vaccine-related causation is wanting, petitioner does not prevail on prong one of the Althen analysis.

2. Examining the Logic of the Proposed Causal Sequence under Prong Two

Prong two of Althen requires petitioner to establish a "logical sequence of cause and effect" between the received vaccine and the suffered injury. See Althen, 418 F.3d at 1278. Petitioner must show that the vaccine was the reason for (or the "but for" cause of) the sustained injury. See Pafford 451 F.3d at 1356; Capizzano, 440 F.3d 1317, 1326

(Fed. Cir. 2006); Shyface v. Sec'y of Dep't of Health & Human Servs., 167 F.3d 1344, 1353 (Fed. Cir. 1999). This requirement has been interpreted to present the question of "did the vaccine at issue cause the injury alleged?" Pafford v. Sec'y of Dep't of Health & Human Servs., No. 01-165V, 2004 WL 1717359, *9 (Fed. Cl. Spec. Mstr. July 16, 2004), aff'd, 451 F.3d 1352 (Fed. Cir. 2006).

Petitioners need not present evidence of "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific of medical communities to establish a logical sequence of cause and effect . . . ." Capizzano, 440 F.3d at 1325. Rather, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Capizzano, 440 F.3d at 1325-26; Andreu, 569 F.3d at 1375-77 (treating physician testimony); see also § 300aa-13(a)(1).

The undersigned has found petitioner's theory of general causation wanting, a finding that precludes a finding of entitlement to compensation under the Vaccine Program. Out of an abundance of caution, however, the undersigned addresses petitioner's theory of specific causation.

In support of Dr. Tornatore's medical opinion that petitioner suffered a vaccine-related inflammatory event that led to one-sided weakness and pain, he relied chiefly on two test results that were positive—specifically, for particular antibodies (ANAs) and for an elevated bilirubin level—shortly after petitioner's vaccination but were negative on all further testing. In the absence of any other objective evidence through either laboratory testing or on magnetic resonance imaging, the two positive test results provide evidence of, at best, non-specific findings and thus, provide limited support for petitioner's claim.

To be weighed against this circumscribed evidence in support of petitioner's position are the repeated notations made by different examiners in petitioner's medical records regarding the absence of medical evidence to support her persistent neurological complaints. On examination, petitioner performed tasks that were strikingly inconsistent with her reported weakness and pain, and her examiners described her alleged condition variously as "bizarre," "embellished," or "factitious." Petitioner's own expert also conceded that some of the findings reported in her medical records were "difficult to explain." This concession by petitioner's expert as well as the skepticism expressed by both petitioner's treating physicians and respondent's expert sharply call into question whether petitioner in fact did suffer a neurological injury and thus, further militate against a finding of vaccine-related causation in this case. See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1349 (Fed. Cir. 2010) (acknowledging that "the causation question turns on the determination of the injury"); see also Doe 60 v. Sec'y of Health & Human Servs., --- Fed.Cl. ----, 2010 WL 3452366, *28-29, August 05, 2010 (NO. XX-XXXV) (finding that petitioner did not establish that she suffered from any of

the conditions for which she sought compensation, and therefore was not entitled to compensation).

Having heard petitioner and her mother testify concerning petitioner's condition, the undersigned is persuaded that Ms. Jarvis possesses a strong belief that she suffered an adverse reaction to the hepatitis B vaccination she received on October 2, 2000. But, the strength of petitioner's belief alone cannot satisfy petitioner's burden of proof under the Vaccine Act, and the evidence offered in support of petitioner's claim of a vaccine-related neurological injury falls substantially short of preponderant evidence.[24] The undersigned is not persuaded that petitioner has made the requisite "more likely than not" showing in this case that she suffered the alleged injury as a result of the administered vaccination and thus, determines that petitioner has failed to establish prong two of Althen.

3. Examining the Temporal Relationship under Prong Three

Prong three of Althen requires petitioner to show that "a proximate temporal relationship" exists between the vaccination and the injury. See Althen, 418 F.3d at 1278. Petitioner must present evidence that the injury occurred within a medically acceptable time frame to link the injury to the received vaccine. See Pafford, 451 F.3d at 1358-1359.

Dr. Tornatore asserts that petitioner developed vaccine-related one-sided weakness almost two weeks after she suffered an initial allergic reaction to the second hepatitis B vaccination she received. See Tr. II at 57. He maintains that the timing of the development of petitioner's various symptoms, particularly the weakness and pain of which she complained, is "right" for the neurological injury petitioner claims to have suffered. Id. Respondent's expert did not rebut Dr. Tornatore's claim that two weeks between a precipitating event—such as the vaccination in the case—and the appearance

[24] Numerous physicians who have examined petitioner over time have suggested that petitioner's symptoms may have a psychiatric basis and have recommended that petitioner undergo psychiatric evaluation. Consistent with those recorded impressions by petitioner's treating doctors, the undersigned urged petitioner's counsel to explore the possibility that petitioner may have begun to exhibit symptoms of a factitious disorder as a result of her vaccinations. Counsel declined to do so electing instead to show that petitioner had suffered a neurological injury rather than a psychiatric one. See Vaccine Rule 3(b)(2) regarding the responsibility of the special master to "endeavor[] to make the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision." Rules of the Court of Federal Claims (RCFC), Appendix (App.) B, Vaccine Rule 3(b)(2).

of an immune-mediated neurological injury falls within the "right" time frame medically. Accordingly, the undersigned finds that petitioner has demonstrated an appropriate temporal relationship exists between her vaccination and her alleged injury.

Notwithstanding the finding that the timing of the alleged injury was medically appropriate, petitioner's claim necessarily must fail under an Althen analysis because petitioner has failed to show her second hepatitis B vaccination more likely than not led to a neurological injury. See Grant, 956 F.2d at 1148 (recognizing that a temporal association, without more, is not sufficient to prove causation).

VII. Conclusion

For the foregoing reasons, petitioner has not established that she suffered a vaccine-related injury. Accordingly, petitioner's claim for Program compensation fails. The petition **SHALL BE DISMISSED**, and the Clerk of Court shall enter judgment consistent with this decision.[25]

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Special Master

[25] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.